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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

- - -

IN RE: ETHICON, INC. : MDL NO. 2327
PELVIC REPAIR SYSTEM, :
PRODUCTS LIABILITY :
LITIGATION :

- - -

THIS DOCUMENT RELATES TO ALL CASES

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June 26, 2013

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Videotaped deposition of PIET HINOUL, M.D., Ph.D. taken pursuant to notice, was held at the law offices of Riker Danzig Scherer Hyland & Perretti LLP, Headquarters Plaza, One Speedwell Avenue, Morristown, New Jersey, beginning at 9:11 a.m., on the above date, before Ann Marie Mitchell, a Federally Approved Certified Realtime Reporter, Registered Diplomate Reporter and Notary Public for the State of New Jersey.

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GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph|917.951.5672 fax
deps@golkow.com

EXHIBIT F

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<p>1 A. At some point the branch within the</p> <p>2 FDA that we had to submit our applications to</p> <p>3 changed. And we had -- initially we were under the</p> <p>4 reconstructive surgery branch, and that was moved to</p> <p>5 the gynecology/obstetrics branch. And these were</p> <p>6 people that were absolutely not informed about these</p> <p>7 devices, about these procedures. So we reached out</p> <p>8 to them to educate them on what products we had and</p> <p>9 what our evidence was behind it. That was certainly</p> <p>10 not lobbying.</p> <p>11 Q. So you went to educate the FDA about</p> <p>12 your products?</p> <p>13 A. And our perspectives, yes.</p> <p>14 Q. And that was a number of people at</p> <p>15 FDA -- at Ethicon that went to this, to educate the</p> <p>16 FDA. Right?</p> <p>17 A. Yes.</p> <p>18 Q. And in fact, you did a PowerPoint for</p> <p>19 that, didn't you?</p> <p>20 A. I did part of the PowerPoint, yes.</p> <p>21 Q. Right. We'll get to that later.</p> <p>22 Now, in terms of your presentation to</p> <p>23 the FDA, did you get an award for that, a company</p> <p>24 award?</p> <p>25 A. I got an award for -- yes, I did get</p>	<p>1 afterwards. Right?</p> <p>2 A. Yes.</p> <p>3 Q. That was at the company in New</p> <p>4 Jersey?</p> <p>5 A. Correct.</p> <p>6 Q. Who was present?</p> <p>7 A. I think there were about 10-15 people</p> <p>8 present, most of the people that we had collaborated</p> <p>9 with in preparation of these meetings. And I</p> <p>10 believe Lesley Fronio was certainly there. Bridget</p> <p>11 Welch, the president, may also have been there.</p> <p>12 Q. Was this after the FDA had announced</p> <p>13 what it was going to do or before? Didn't the FDA</p> <p>14 take some action after this meeting, this panel</p> <p>15 meeting?</p> <p>16 A. Well, much later they decided to</p> <p>17 issue 522 orders. This is much before then.</p> <p>18 Q. So this was just --</p> <p>19 Before there was a result, before</p> <p>20 anybody knew what the FDA was going to do, you got a</p> <p>21 leadership award. Right?</p> <p>22 A. Yes.</p> <p>23 Q. And who were the other people who got</p> <p>24 leadership awards?</p> <p>25 A. I certainly remember Brian Kanerviko,</p>
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<p>1 an award for that.</p> <p>2 Q. Right.</p> <p>3 It's the global leadership award.</p> <p>4 Right?</p> <p>5 A. Yes.</p> <p>6 Q. If you'll go over to page 6 again of</p> <p>7 your --</p> <p>8 How did you get that award?</p> <p>9 A. How did I get that award?</p> <p>10 Q. Yeah. What were the circumstances</p> <p>11 to -- how was it announced?</p> <p>12 A. There was a small meeting afterwards</p> <p>13 over lunch, and we were awarded -- we were awarded</p> <p>14 these -- several people, because the lot of work</p> <p>15 that involved in preparing for these meetings.</p> <p>16 Q. Who made the award to you?</p> <p>17 A. I think it was Lesley Fronio. Lesley</p> <p>18 Fronio, and it's given to you by two leaders, Lesley</p> <p>19 Fronio and Gary Pruden are on the award, I think.</p> <p>20 Q. So is it a plaque or what?</p> <p>21 A. It's a piece of paper.</p> <p>22 Q. And that was given to you while you</p> <p>23 were still in Washington, DC?</p> <p>24 A. No.</p> <p>25 Q. You said in a small meeting</p>	<p>1 who was my regulatory counterpart at the time.</p> <p>2 There may have been others.</p> <p>3 Q. Now, you mentioned that these -- this</p> <p>4 award was on behalf of Lesley Fronio --</p> <p>5 A. Lesley Fronio.</p> <p>6 Q. I'm sorry, Fronio. Lesley Fronio and</p> <p>7 Gary Pruden. Correct?</p> <p>8 A. Yes.</p> <p>9 Q. And what were their positions at</p> <p>10 Ethicon at the time you got this award?</p> <p>11 A. Unfortunately, we -- they change so</p> <p>12 often in title that I may get it wrong. I think</p> <p>13 Gary Pruden was company group chairman of Ethicon at</p> <p>14 the time and Lesley Fronio was the vice president of</p> <p>15 marketing.</p> <p>16 Q. So the vice president of marketing</p> <p>17 and the chairman -- I assume that's a pretty high</p> <p>18 position.</p> <p>19 Chairman of what?</p> <p>20 A. Company group chairman of Ethicon.</p> <p>21 Q. Is that the highest level position in</p> <p>22 Ethicon at the time?</p> <p>23 A. I think so, yes.</p> <p>24 Q. So that was the person who was at the</p> <p>25 complete top of the company ladder at Ethicon.</p>

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<p>1 Right?</p> <p>2 A. Yes.</p> <p>3 Q. So he, along with the group, where</p> <p>4 the vice president of marketing awarded you the</p> <p>5 leadership award for your work in presenting on</p> <p>6 behalf of the company and the industry at FDA.</p> <p>7 Right?</p> <p>8 A. Yes. But I was awarded for what I</p> <p>9 did for the company, how I represented the company.</p> <p>10 Q. So it had to do with how you</p> <p>11 represented the company, not how you represented</p> <p>12 industry. Right?</p> <p>13 A. That was how I did it, but my prize</p> <p>14 was for what I did for the company or how I</p> <p>15 represented the company in that setup.</p> <p>16 Q. Now, in your resume, it looks like</p> <p>17 you -- it says here you got another global</p> <p>18 leadership award in 2012. Right?</p> <p>19 A. Yes.</p> <p>20 Q. And this says, at the bottom there,</p> <p>21 it says, "And one in 2012 for my work on the exit of</p> <p>22 a category of products (pelvic organ prolapse mesh</p> <p>23 kits)." Do you see that?</p> <p>24 A. Yes.</p> <p>25 Q. So you were awarded a leadership</p>	<p>1 getting a global leadership award to help get the</p> <p>2 pelvic organ mesh kits removed from the market?</p> <p>3 A. Right. So I was recognized in this</p> <p>4 prize for the fact that I represented the surgical</p> <p>5 community, but especially the patient, because I was</p> <p>6 in disagreement with the ceasing of the</p> <p>7 commercialization. I felt that these products</p> <p>8 brought tremendous value to patients. I had treated</p> <p>9 thousands of patients with these products, and I</p> <p>10 felt that it would be a pity to stop doing that.</p> <p>11 And so I was awarded for my credo values that were</p> <p>12 displayed during that period.</p> <p>13 Q. So if it was up to you, the mesh kits</p> <p>14 would still be sold. Right?</p> <p>15 A. That's correct.</p> <p>16 Q. So your viewpoint at the time and</p> <p>17 today is that Prolift --</p> <p>18 A. Yes.</p> <p>19 Q. -- should still be on the market?</p> <p>20 A. Absolutely.</p> <p>21 Q. And you got awarded a prize by the</p> <p>22 company for taking that position. Right?</p> <p>23 A. Yes.</p> <p>24 Q. Now, in fact, you were --</p> <p>25 When you actually looked at what</p>
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<p>1 award, a global leadership reward, for your</p> <p>2 involvement in the removal of the pelvic organ</p> <p>3 prolapse kits from the market. Right?</p> <p>4 A. We stopped commercializing them, and</p> <p>5 that involved a lot of work. And I was indeed</p> <p>6 awarded another prize for that.</p> <p>7 Q. Well, do these prizes come along with</p> <p>8 any promotions or cash awards or anything like that?</p> <p>9 A. There is a small amount, a cash</p> <p>10 amount, that is involved with getting such a</p> <p>11 leadership award.</p> <p>12 Q. What is the small cash amount?</p> <p>13 A. I don't remember. It may be a</p> <p>14 thousand dollars, something of that magnitude.</p> <p>15 Q. What work did you do in order to get</p> <p>16 the pelvic organ mesh kits off the market that led</p> <p>17 to you getting a leadership award?</p> <p>18 MS. JONES: I'm sorry, Counsel, would</p> <p>19 you mind repeating that?</p> <p>20 MR. BLIZZARD: Yeah.</p> <p>21 MS. JONES: I just didn't -- I lost</p> <p>22 it and I've lost my feed here.</p> <p>23 MR. BLIZZARD: Sure, sure.</p> <p>24 BY MR. BLIZZARD:</p> <p>25 Q. What work did you do that led to you</p>	<p>1 evidence there was, or the lack of evidence, lack of</p> <p>2 high grade evidence, for the safety and efficacy of</p> <p>3 mesh kits, you were astonished, weren't you?</p> <p>4 MS. JONES: Object to the form.</p> <p>5 THE WITNESS: Absolutely not. And</p> <p>6 what lack of evidence are you talking about?</p> <p>7 BY MR. BLIZZARD:</p> <p>8 Q. Well, before you ever went to work</p> <p>9 for the company, didn't you look at what evidence</p> <p>10 was out there to support the safety and efficacy of</p> <p>11 mesh kits?</p> <p>12 A. Before I worked for the company?</p> <p>13 Q. Yes.</p> <p>14 A. Yes.</p> <p>15 Q. You looked at that issue, didn't you?</p> <p>16 You looked at what the evidence was for their safety</p> <p>17 and efficacy, didn't you?</p> <p>18 A. Yes.</p> <p>19 Q. And when you actually examined the</p> <p>20 evidence for mesh kits, you found that there was a</p> <p>21 paucity of evidence, didn't you?</p> <p>22 MS. JONES: Object to the form.</p> <p>23 THE WITNESS: Well, it depends on</p> <p>24 what time period you're talking on.</p> <p>25 BY MR. BLIZZARD:</p>